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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,696

11/04/2005

Susana Salceda

DEX-0522

4625

32800

7590

08/10/2007

LICATA & TYRRELL P.C.

66 E. MAIN STREET

MARLTON, NJ 08053

EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,696

Applicant(s)

SALCEDA ET AL.

Examiner

James Martinell

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of the requirement for restriction in the reply filed on June 28, 2007 is acknowledged. The traversal is on the ground(s) that applicants believe that Groups I-III share a common special technical feature and that a search of the art related to an elected nucleic acid sequence should reveal art relating to the protein encoded thereby. This is not found persuasive because applicants do not point out, with particularity, the common special technical feature shared by the inventions of Groups I-III. Applicants do not point to any common special technical feature shared by any two of the dozens of nucleic acid sequences and polypeptide sequences mentioned in the claims. That prior art relevant to a claim to a polypeptide may be found in a search of a nucleic acid that encodes that polypeptide does not show that no burden exists in searching the two inventions since the searches are not coextensive. Likewise, a search of the nucleic acids that encode a polypeptide is not coextensive with a search for antibodies that may bind to the polypeptide encoded by the nucleic acids. The requirement is still deemed proper and is therefore made FINAL.

Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 28, 2007.

Claims 11-14 should be identified as "(Withdrawn)" in applicants' next response. See 37 CFR § 1.121(c)(2).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

- (a) Claims 1, 15, and 16 are vague and indefinite because they claim more than was elected.

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- (b) The recitation of "selectively hybridizes" (claim 1) is vague and indefinite because selective hybridization depends upon the presence or absence of cross-hybridizing molecules in the reaction mixture. Since no particular reaction mixture is recited in the claim, the metes and bounds of the claim are not clear.
- (c) The recitation of "selectively hybridize" (claim 7) is vague and indefinite because selective hybridization depends upon the presence or absence of cross-hybridizing molecules in the reaction mixture. Since no particular reaction mixture is recited in the claim, the metes and bounds of the claim are not clear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 2, 4-10, and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gendler et al (J. Biol. Chem. 265: 15286 (1990)). Gendler et al discloses a human breast cancer associated nucleic acid (*e.g.*, see Abstract, Figures 1-3, and pages 15290-15291) that shares 298 contiguous nucleotides with SEQ ID NO: 36 of the instant claims. See the alignment below. The nucleic acid of Gendler et al would hybridize to SEQ ID NO: 36 of the instant claims. Kennell (paragraph bridging pages 260-261) is cited to show that a heteroduplex of 25-50 base pairs is maximally stable, and would thus form a specific hybrid in nucleic acid molecular hybridization reaction (Kennell (Progr. Nucl. Acid Res. Mol. Biol. 11: 259 (1971))).

Alignment of SEQ ID NO: 36 with Gendler et al (J. Biol. Chem. 265: 15286 (1990)), Figure 1

HUMMUCAB
LOCUS HUMMUCAB 1804 bp mRNA linear PRI 07-JAN-1995
DEFINITION Human polymorphic epithelial mucin (PEM) mRNA, complete cds.
ACCESSION J05581
VERSION J05581.1 GI:188869
KEYWORDS polymorphic epithelial mucin.
SOURCE Homo sapiens (human)
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
Catarrhini; Hominidae; Homo.
REFERENCE 1 (bases 1 to 1804)
AUTHORS Gendler,S.J., Lancaster,C.A., Taylor-Papadimitriou,J., Duhig,T.,
Peat,N., Burchell,J., Pemberton,L., Lalani,E.N. and Wilson,D.
TITLE Molecular cloning and expression of human tumor-associated
polymorphic epithelial mucin
JOURNAL J. Biol. Chem. 265 (25), 15286-15293 (1990)
PUBMED 1697589
COMMENT Original source text: Homo sapiens adult adenocarcinoma cDNA to
mRNA.
Draft entry and computer-readable sequence for [J. Biol. Chem.
(1990) In press] kindly submitted
by S.J.Gendler, 26-JUN-1990.

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Query Match 38.5%; Score 298; DB 5; Length 1804;
 Best Local Similarity 100.0%; Pred. No. 6.5e-154;
 Matches 298; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy      283 CCCGGGATACCTACCATCCTATGAGCGAGTACCCACCTACCACACCCATGGGCGCTATG 342
      |||
Db     1328 CCCGGGATACCTACCATCCTATGAGCGAGTACCCACCTACCACACCCATGGGCGCTATG 1387

Qy      343 TGCCCCCTAGCAGTACCGATCGTAGCCCTATGAGAAGGTTTCTGCAGGTAATGGTGGCA 402
      |||
Db     1388 TGCCCCCTAGCAGTACCGATCGTAGCCCTATGAGAAGGTTTCTGCAGGTAATGGTGGCA 1447

Qy      403 GCAGCCTCTCTTACACAAACCCAGCAGTGGCAGCCACTTCTGCCAACTTGTAGGGGCACG 462
      |||
Db     1448 GCAGCCTCTCTTACACAAACCCAGCAGTGGCAGCCACTTCTGCCAACTTGTAGGGGCACG 1507

Qy      463 TCGCCCGCTGAGCTGAGTGAGTGCCAGCCAGTGCCATTCCACTCCACTCAGGTTCTTCAGGGC 522
      |||
Db     1508 TCGCCCGCTGAGCTGAGTGAGTGCCAGCCAGTGCCATTCCACTCCACTCAGGTTCTTCAGGGC 1567

Qy      523 CAGAGCCCCTGCACCCTGTTTGGGCTGGTGAGCTGGGAGTTCAGGTGGGCTGCTCACA 580
      |||
Db     1568 CAGAGCCCCTGCACCCTGTTTGGGCTGGTGAGCTGGGAGTTCAGGTGGGCTGCTCACA 1625

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Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gendler et al (J. Biol. Chem. 265: 15286 (1990)) in view of applicants' admitted state of the prior art (*e.g.*, instant application, page 42, line 8 through page 43, line 7). The discussion of Gendler et al above is incorporated here. Applicants acknowledge (instant application, page 42, line 8 through page 43, line 7) the isolation of genomic DNA once cDNA has been isolated to be old. It would have been obvious for one of ordinary skill in the art at the time the invention was made to isolate genomic DNA from the cDNA of Gendler et al in order to identify the chromosomal (genomic) DNA sequences that encode the cDNA of Gendler et al using the admittedly old methods.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gendler et al (J. Biol. Chem. 265: 15286 (1990)) in view of An et al (U.S. Patent No. 6,218,529). The discussion of Gendler et al above is incorporated here. An et al teaches the use of tumor-specific nucleic acid markers for cancers, including breast cancers (*e.g.*, see Figure 15; column 5, line 16 through column 8, line 5; column 10, lines 26-29; column 10, line 62 through column 11, line 37; and column 29, line 65 through column 30, line 9). It would have been obvious for one of ordinary skill in the art at the time the

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invention was made to use the human breast cancer associated nucleic acid of Gendler et al as a cancer marker in the manner taught by An et al in order to detect and/or diagnose breast cancers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.


OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1634
8/2/07